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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,205	11/28/2001	Rina K. Dukor	214346	1255
23460	7590	04/02/2004	EXAMINER	
LEYDIG VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6780			WALLENHORST, MAUREEN	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/996,205

Applicant(s)

DUKOR ET AL.

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☒ Claim(s) 6-16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

1. Applicant's election of Group I, claim 1-16 in the response filed on December 19, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Rava et al.

Rava et al teach of a method using molecular spectroscopy to diagnose the condition of a tissue. In the method, the various stages of atherosclerosis in human aorta samples are differentiated using infrared Fourier transform (FT) Raman spectroscopy. A sample of a human aorta is obtained and subjected to FT-Raman spectroscopy. The sample is composed of three layers. The innermost layer is composed mostly of collagen fibers. The medial layer contains

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mostly the protein elastin, and the outermost layer serves as a connective tissue network made up of mostly lipids, lipoproteins and collagen. Therefore, Rava et al teach of a method comprising the steps of identifying a region in a biological sample containing extracellular material (i.e. the connective tissue and collagen fibers of the aorta sample), and obtaining infrared absorbance spectral data from the region containing the extracellular material. The presence of spectral markers that serve to differentiate normal from diseased aortas are identified. See lines 36-48 in column 7 of Rava et al where different spectral bands that are different between normal and diseased aortas are identified. In addition, see lines 10-35 in column 7 and lines 18-30 in column 8 of Rava et al.

5. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Camacho et al.

Camacho et al teach of a method for evaluating the ultrastructure of connective tissue such as cartilage by obtaining infrared absorbance spectral data therefrom. Camacho et al teach that cartilage is composed of a network of collagen fibrils, non-collagenous proteins and proteoglycan components. Therefore, Camacho et al teach of a method comprising the steps of identifying a region in a biological sample containing extracellular material (i.e. the connective tissue of cartilage), and detecting mid-infrared or near-infrared radiation that penetrates the surface of the connective tissue. The infrared radiation is analyzed for peak height, peak area and frequency and compared to established values for normal connective tissue to detect a modification in the molecular structure of the connective tissue analyzed. A normal connective tissue will have a signature spectrum that is comprised of absorbance peaks at specific frequencies and of specific heights and/or areas. The spectrum of a diseased or modified connective tissue will be altered from the normal, whereby there are changes in the peak heights,

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areas or frequencies. Camacho et al teach that specific changes in IR bands have been discovered that are linked to the disease and degradation of cartilage. These specific changes serve as spectral markers for the indication of pathology in a connective tissue. See paragraph nos. 24-27, 45, 50-59 and 61 of Camacho et al.

6. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong (US Patent no. 5,539,207, submitted in the Information Disclosure Statement filed on December 19, 2003).

Wong teaches of a method for identifying tissue by determining the infrared spectrum of a tissue sample in at least one frequency band, and comparing the IR spectrum of the sample to a library of stored infrared spectra of known tissue types to find the closest match. Wong also teaches of a method for detecting pathology such as colon cancer in a biopsy from the colon by obtaining the infrared spectrum from the biopsy and comparing it to normal colon tissue and malignant colon tissue. Since the infrared spectra are significantly different among the normal tissues and the malignant tissues, the infrared pattern of a sample biopsy can be unambiguously diagnosed as negative or positive depending upon which type of spectra it matches more closely to. See lines 38-52 in column 8 of Wong. Wong teaches that both colon cancer and cervical cancer can be diagnosed using this method. The sample tissue type analyzed can be a connective tissue, which is mainly composed of extracellular matrix. Wong teaches that the IR spectrum for connective tissue is different than the IR spectrum for epithelial tissue and from colon or cervical cells. Wong teaches that spectral markers exist in the IR spectrum for normal connective tissue such as at 1283 cm⁻¹ that are not observed in the IR spectrum of malignant tissues. See Figures 1 and 2 in Wong where the IR spectra of connective tissue containing extracellular material is compared to the IR spectra of both normal and malignant tissues.

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7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wong in view of Dukor (US Patent no. 5,945,674). For a teaching of Wong, see previous paragraphs in this Office action. Wong fails to teach that breast cancer can be diagnosed with the method by obtaining the IR spectrum of a breast connective tissue sample and comparing it to the IR spectrum of both a normal and malignant breast sample.

Dukor teaches of a method for diagnosing breast cancer in a breast biopsy sample by directing an infrared beam to the breast biopsy sample, detecting the IR light reflected by the sample and analyzing the IR light reflected to identify cellular types in the sample. See Figure 4 in Dukor that shows the infrared spectra of benign, hyperplastic and malignant cells in breast tissue samples.

Based upon the combination of Wong and Dukor, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to analyze the IR spectrum of

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connective tissue in breast biopsy specimens using the method of Wong since Dukor teaches that it is known to diagnose breast cancer in breast biopsy specimens using a comparison of the IR spectrum from the breast biopsy specimen to both normal and diseased IR spectra, and Wong teaches that changes/markers in the IR spectra of connective tissue between normal and diseased specimens can be used to detect pathologies.

10. Claims 6-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims since none of the prior art of record teaches or fairly suggests a method for diagnosing the presence of a pathology in a biological sample by obtaining infrared absorbance spectral data from a region containing extracellular material and determining from the infrared absorbance spectral data whether an infrared spectral marker is found in the region containing the extracellular material, wherein the step of determining includes calculating a slope of a baseline of the infrared absorbance spectral band at about 1280 cm^{-1} from IR spectral intensities of first and second baseline point wavenumbers that are greater than and smaller than 1280 cm^{-1} , specifically where the baseline point wavenumbers are 1303 cm^{-1} and 1264 cm^{-1} .

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Cohenford et al who teach of a method for the detection of cellular abnormalities using fourier transform infrared spectroscopy; and Dukor et al (US patent no. 6,274,871) who teach of a method for performing fourier transform infrared spectroscopy on biological samples. The reference to Dukor et al does not qualify as prior art against the instant claims under either 35 USC 102(b) or 35 USC 102(e) since this reference has the same inventive

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entity as the instant application and was published after the effective filing date of the instant application.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

March 29, 2004

Maureen M. Wallenhorst
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PRIMARY EXAMINER
GROUP 1200 1700